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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,538	06/10/2002	Thomas N. Masters	38151/203996	6926

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EXAMINER

MITCHELL, GREGORY W

ART UNIT PAPER NUMBER

1617

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/088,538

Applicant(s)

MASTERS, THOMAS N.

Examiner

Gregory W. Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6,7 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,7 and 9-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

5.8.0

### DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed June 20, 2005. Claim 6 has been amended. Claims 6, 7 and 9-14 are pending and are examined herein. Applicant's amendments have necessitated the withdrawal of the rejection set forth in the previous Office Action. The following rejections now apply.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massoudy et al. (*J. Mol. Cell. Cardiol.* 29, 535-544) in view of Raymond (USPN 5693462).

Massoudy et al. teaches that cyclosporine A acts as a cardioprotective agent in ischemia and reperfusion (Abstract). Cyclosporine A, in concentrations of 0.8  $\mu\text{m}$  in Krebs-Henseleit buffer, was shown to significantly prevent the loss of post-ischemic cardiac function in isolated hearts (p. 536, col. 2, last ¶; p. 539, col. 2, 1<sup>st</sup> ¶). The reference does not teach the preferred concentration.

Raymond teaches the components of the Krebs-Henseleit buffer as comprising those components as instantly claimed (col. 4, lines 15-33).

It would have been obvious, absent a showing of unexpected results, to one of ordinary skill in the art at the time of the invention to treat an isolated heart with a composition comprising the claimed amount of cyclosporine A because Massoudy et al. teaches that such compositions are useful at preserving the heart and "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is noted that it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the compositions of Massoudy et al. in treating a heart prior to transplantation because, as taught by Massoudy et al., such a treatment significantly prevents the loss of post-ischemic cardiac function. Accordingly, one would have been motivated to treat hearts awaiting transplantation to preserve the cardiac function thereof.

It is also noted that the methods of Massoudy et al. and those as instantly claimed are both directed to preserving of a heart. Accordingly, the composition rendered obvious by the combined references would obviously block apoptosis because the same composition administered for the same purpose will obviously function via the same mechanism, whether or not that mechanism is disclosed in the prior art.

### ***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments, as pertinent to the instant rejection, are addressed below.

Applicant's arguments that the "active ingredients of the Raymond solution materially affect its properties ...". Accordingly, Applicant argues, the closed language of "consisting essentially of" precludes their combination with the claimed composition. This argument is not persuasive because Examiner no longer relies on the addition of cyclosporin A to the composition of Raymond. Raymond is merely used to illustrate the components that comprise the Krebs-Henseleit buffer.

Applicant's arguments that "cyclosporin A is used to concentrations of 0.08  $\mu$ M and 0.8  $\mu$ M which is the effective plasma level required in patients after heart transplantation." This argument is not persuasive because, as discussed above, Massoudy et al. teaches the treatment of *isolated* hearts.

Applicant argues, "[t]he lower level of CSA used in the present invention is at least three times the amount of CSA disclosed in Massoudy *et al.*" This argument is not persuasive absent a showing of unexpected results because it would have been obvious to one of ordinary skill in the art that increasing the concentration would be at least as effective as the lower concentrations of Massoudy et al. Furthermore, Massoudy et al. uses the concentrations as examples in experimentation. The skilled artisan would not recognize these as limitations on the concentrations useful in the preparation of a composition for the preservation of a heart. It is well established that

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consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to a person of ordinary skill in the art. *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966); *In re Lamberti*, 545 F.2d 747, 19USPQ 279 (CCPA 1976); *In re Fracalossi*, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

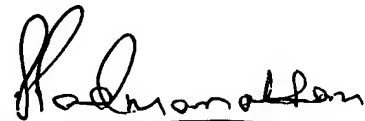
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**